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L2	L1 and (topical$ or transdermal$)	44	L2
L1	(peripheral) adj1 (vascular or arterial) same liposom$	52	L1

END OF SEARCH HISTORY

L2: Entry 33 of 44 File: PGPB Oct 30, 2003

DOCUMENT-IDENTIFIER: US 20030202960 A1
TITLE: Therapeutic angiogenic factors and methods for their use

Abstract Paragraph:
Methods are provided for stimulating angiogenesis in a human or animal in need thereof. Also provided are compositions comprising an angiogenic factor in a pharmaceutically acceptable carrier. In one embodiment, the method comprises administering to the human or other animal a therapeutically effective amount of an angiogenic factor, such as a pleiotrophin or midkine protein, in a pharmaceutically acceptable carrier. The carrier in one embodiment comprises a controlled release matrix, such as a polymer, that permits controlled release of the angiogenic factor. The polymer may be biodegradable and/or bioerodible and preferably biocompatible. Polymers which may be used for controlled release include, for example, poly(esters), poly(anhydrides), and poly(amino acids). Exemplary polymers include silk elastin poly(amino acid) block copolymers and poly-lactide-co-glycolide. In a further embodiment, the angiogenic factor may be provided in a carrier comprising a liposome, such as a heterovesicular liposome. The carrier, such as a liposome, may be provided with a targeting ligand capable of targeting the carrier to a preselected site in the body. The angiogenic factor may be administered to the vascular system, for example the cardiovascular system, or the peripheral vascular system. In a preferred embodiment, the angiogenic factor is a pleiotrophin protein, or a midkine protein. In another embodiment, a method is provided for stimulating angiogenesis in a human or animal comprising administering a therapeutically effective amount of a gene transfer vector encoding the production of pleiotrophin or midkine protein in a pharmaceutically acceptable carrier. The gene transfer vector may be, for example, naked DNA or a viral vector, and may be administered, for example, in combination with liposomes.

Detail Description Paragraph:
[0065] The angiogenic factor, optionally in a carrier, or formulation thereof, may be administered by a variety of routes known in the art including topical, oral, parenteral (including intravenous, intraperitoneal, intramuscular and subcutaneous injection as well as intranasal or inhalation administration) and implantation. The delivery may be systemic, regional, or local. Additionally, the delivery may be intrathecal, e.g., for CNS delivery. For example, administration of the angiogenic factor for the treatment of wounds may be by topical application of the angiogenic factor to the wound, systemic administration by enteral or parenteral routes, or local or regional injection or implantation. The angiogenic factor may be formulated into appropriate forms for different routes of administration as described in the aft, for example, in "Remington: The Science and Practice of Pharmacy", Mack Publishing Company, Pennsylvania, 1995, the disclosure of which is incorporated herein by reference.

Detail Description Paragraph:
[0072] The angiogenic factor also may be administered by administering a nucleic acid encoding for the angiogenic factor. Nucleic acid polymers encoding angiogenic factors thus may be administered therapeutically. Nucleic acid polymers (DNA or RNA) encoding angiogenic factors are incorporated into nucleic acid constructs (gene transfer vectors), which include the appropriate signals (e.g., enhancers, promoters, intron processing signals, stop signals, poly-A addition sites, etc.)

for the production of the angiogenic factor in the cells of the patient. The angiogenic factor-encoding nucleic acid constructs may be delivered systemically, regionally, locally, or topically, preferably delivered topically, locally or regionally, to induce production of the angiogenic factors by cells of the patient's body. Alternately, the angiogenic factor-encoding nucleic acid constructs may be delivered to a remote site, which will produce angiogenic factor and allow for its dispersal throughout the patient's body.

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L2: Entry 41 of 44 File: USPT Nov 30, 1999

DOCUMENT-IDENTIFIER: US 5993851 A
TITLE: Method for preparing biphasic multilamellar lipid vesicles

Brief Summary Text (4):
Liposomes are prime candidates for the systemic as well as topical delivery of drugs. Several studies showed that liposome encapsulation advantageously alters the pharmacokinetic fate of the drug after topical application. The first experimental evidence that liposomes may penetrate into the skin and deposit within the dermis was obtained recently by using a novel small particle-size electrondense marker (colloidal iron), which can be efficiently encapsulated into liposomes of various sizes and compositions, and can be easily identified in cells and tissues by electron microscope.

Brief Summary Text (14):
Prostaglandin E.sub.1 (PGE.sub.1), a potent relaxant of the vascular smooth muscle, has been shown to be effective and safe in the treatment of impotence by increasing arterial inflow through vasodilatation and decreasing venous outflow by the occlusion of draining venules due to relaxation of corporal smooth muscle. As opposed to other previously used drugs such as papaverine or phentolamine, PGE.sub.1 is not as frequently associated with the common side effects e.g. priapism, plaques at the injection site and liver function abnormalities, therefore it is clinically more acceptable. PGE.sub.1 is usually self-injected into the corpus cavernosum through the lateral aspect of the shaft of the penis. This type of administration, however, is associated with penile discomfort, pain at the injection site and the inconvenience of application prior to intercourse. Topical application of PGE.sub.1 would be an ideal route of administration, however, the drug itself (without a delivery system) cannot penetrate the skin in adequate concentration and would be metabolized within the skin very quickly before reaching the underlying tissues.

Brief Summary Text (18):
Interferon has activity against papillomaviruses, and cures infected cells by eliminating extrachromosomal viral DNA. Systemic application (i.m. injection) of interferon alpha in patients with genital warts was shown to be fairly successful, however it is associated with various side effects such as fever, myalgias, headache, nausea, fatigue. Intralesional IFN treatment appears to be a more promising approach for visible lesions, but it is not suitable for latent or subclinical infections. Initially highly positive results (90% complete response) were reported with topical natural leukocyte IFN. Vesterinen et al. reported colposcopic remission in five out of eight patients with vaginal flat condylomas treated with a potent topical IFN cream. However, in spite of the improvement of clinical appearance, the cytology remained positive in all cases and two responding patients had recurrences in two months.

Brief Summary Text (41):
Multilamellar lipid vesicles within the scope of the present invention can be used particularly for topical applications. When the preferred process for making vesicles is used the peripheral compartments comprise at least traces of a pharmaceutically acceptable hydrophilic solvent and the obtained multilamellar lipid vesicles are devoid of traces of toxic organic solvents, such as chloroform

or methanol, which are usually employed in conventional liposome-forming techniques for dissolving the liposome-forming component. It is noted that the vesicles are composed entirely, or almost entirely, of materials that occur in nature and are compatible with skin.

Brief Summary Text (44):
Also within the scope of the invention is a method for the treatment of erectile dysfunction. This method comprises topically administering to a patient in need thereof an effective amount of a liposome composition comprising a population of multilamellar lipid vesicles having a prostaglandin, preferably PGE.sub.1, entrapped within the vesicles.

Brief Summary Text (45):
The invention also relates to a method for the treatment of papillomavirus infections. The method comprises topically administering to a patient in need thereof an effective amount of a liposome composition comprising a population of multilamellar lipid vesicles and interferon alpha entrapped within the vesicles.

Brief Summary Text (46):
Also within the scope of the present invention is the use of a topical liposome composition for the application of PGE.sub.1 in the treatment of impotence. The liposome composition comprises a population of multilamellar lipid vesicles containing PGE.sub.1.

Brief Summary Text (48):
Also, the formulation of liposomal IFN has contributed to the development of an effective form of topical interferon, and offers the advantage of treating latent HPV infections as well as visible genital warts. The formulation of liposomal IFN could be administered by the patients at home without the need for multiple painful local or i.m. injections.

Brief Summary Text (50):
A population of multilamellar lipid vesicles in accordance with the invention may have the consistency of a cream, and can therefore be used as such. In the past liposomal formulations have not displayed the consistency of a cream, and it has been necessary to incorporate them in a cream-base or gel matrix to obtain a preparation that is suitable for topical application. With the multilamellar lipid vesicles of the invention use of a cream base or gel matrix may not be necessary, although of course preparations composed of vesicles of the invention and a cream base or gel matrix are not outside the scope of the invention.

Detailed Description Text (2):
The invention relates to liposomal compositions for oral and topical use, particularly for the dermal and transdermal delivery of biologically active compounds including, for example, prostaglandins, proteins, anti-viral agents, anaesthetics, vitamins, herbal extracts and antiinflammatory agents. The liposome compositions of the present invention can be used for the topical administration of biologically active compounds to hairy or hairless areas of the skin. They can also be used in mucus membranes for nasal, buccal, ocular, otic, vaginal and urethral administration. The liposome compositions can also be used for localized (intradermal and intramucosal) or systemic (transdermal or transmucosal) delivery as well as in subcutaneous or intracutaneous injection for slow release depot in or beneath the skin.

Detailed Description Text (8):
The liposomal formulations of the present invention preferably contain saturated and/or unsaturated phospholipids, more preferably phosphatidylcholine, lysophosphatidylcholine, phosphatidylserine, phosphatidylethanolamine, glycolipids and ceramides. The phospholipids are preferably in combination with a penetration enhancing agent such as monolauroyllysine, dipalmitoyllysine or methyl salicylate

to achieve predominantly transdermal delivery potential.

Detailed Description Text (13):
This procedure is suitable for the preparation of various amounts of topical liposomal product. If vortex mixing is used as the agitation, up to about 20 g of the product can be prepared. If a laboratory scale propeller mixer is used, up to about 2000 g of the product can be made. This formulation procedure can also be adapted for large scale manufacturing. Hence, the propeller mixing technique can be directly scaled up by geometrically increasing the size of the vessel and the diameter of the propeller mixer. However, as the vessel size increases, the preferred set up would be a combination mixer i.e a high intensity mixer with propeller mixer and a scraped surface agitator. The aqueous phase is pumped from tank A to tank B containing the anhydrous plastic proliposome gel at the required temperature and mixed. This procedure is suitable for the production of any topical liposomal product on a large scale.

Detailed Description Text (21):
It will be appreciated that biologically active ingredients that are water-soluble can be present in the water of the aqueous emulsion in the central core compartment 9 and in the peripheral compartments 20. Biologically active ingredients that are lipophilic can be present in the dispersed phase of the emulsion in the central compartment 9 and in the peripheral compartments 20. They can also be present in the interior of the lipid bilayers as shown at 21. The biologically active ingredient can constitute the lipophilic droplets 21, or the biologically active ingredient can be dissolved in a lipophilic solvent that forms droplets 21. Thus the invention permits the topical application of biologically active ingredients that are water-soluble or water-insoluble.

Detailed Description Text (25):
FIG. 1 is a scanned image, magnified 440.times. of vesicles made in accordance with product 5, "Topical liposomal product with encapsulated lipophilic drug in multicompartments with encapsulated oil droplet and consistency enhancer" described further below. This product displayed the consistency of a lotion or semi-solid cream. Inspection of the scanned image reveals multilamellar structures with uniform size distribution. These have displayed physical stability for extended periods of time of more than one year.

Detailed Description Text (37):
Overall, the preparation of multilamellar lipid vesicles with a central emulsion core component provides a physically stable, uniform liposome composition. The composition has a viscosity that is suitable for topical administration and can be easily manufactured on a large scale.

Detailed Description Text (46):
1. Topical liposomal product with encapsulated oil droplet

Detailed Description Text (47):
2. Topical liposomal product with encapsulated consistency enhancer

Detailed Description Text (48):
3. Topical liposomal product with encapsulated oil droplet and consistency enhancer

Detailed Description Text (50):
4. Topical liposomal prostaglandin E.sub.1

Detailed Description Text (51):
5. Topical liposomal product with encapsulated lipophilic drug in multicompartments and with encapsulated oil droplet and consistency enhancer

Detailed Description Text (52):
6. Topical liposomal product with encapsulated PGE.sub.1 oil and consistency enhancer

Detailed Description Text (53):
7. Topical liposomal product with PGE.sub.1

Detailed Description Text (54):
8. Topical liposomal product with PGE.sub.1

Detailed Description Text (55):
9. Topical liposomal product with PGE.sub.1

Detailed Description Text (56):
10. Topical liposomal product with PGE.sub.1

Detailed Description Text (57):
11. Topical liposomal product with PGE.sub.1

Detailed Description Text (58):
12. -0.1% Topical liposomal product with PGE.sub.1

Detailed Description Text (59):
13. Topical liposomal product with PGE.sub.1

Detailed Description Text (60):
Of the PGE.sub.1 -containing products, products Nos. 4, 7, 8, 9, 10, 11, 12 and 13 were prepared with an aqueous solution rather than an emulsion. As is demonstrated in products Nos. 5 and 6, however, by incorporating a lipophilic consistency enhancer and a surfactant it is possible to prepare vesicles that have an emulsion in the central core compartment and which display enhanced consistency, rendering them particularly suitable in compositions for topical application.

Detailed Description Text (62):
14. Topical liposomal product with encapsulated lipophilic drug in multicompartments and with encapsulated oil droplet and consistency enhancer

Detailed Description Text (64):
15. Topical liposomal product with encapsulated antiviral drug combination with or without consistency enhancer

Detailed Description Text (66):
16. Topical liposomal product with encapsulated protein drug and with encapsulated oil droplet and consistency enhancer

Detailed Description Text (67):
17. Topical liposomal product with encapsulated protein drug and consistency enhancer

Detailed Description Text (69):
18. Topical liposomal product with encapsulated oily plant extract and consistency enhancer

Detailed Description Text (70):
19. Topical liposomal product with encapsulated oil and oil-soluble cosmetic active ingredient and consistency enhancer

Detailed Description Text (71):
20. Topical liposomal product with encapsulated oil and oil-soluble cosmetic active ingredient and consistency enhancer

Detailed Description Text (73):
21. Topical liposomal product with encapsulated oil-soluble cosmetic active ingredient and consistency enhancer

Detailed Description Text (74):
22. Topical liposomal product with encapsulated oil-soluble cosmetic active ingredients (vitamins) and consistency enhancer

Detailed Description Text (76):
Liposome encapsulated prostaglandins and prostaglandin analogs can provide benefit in a number of treatment areas. The following table summarizes the utility of liposome encapsulated prostaglandins. The advantage of liposomal delivery of these prostaglandins is the more efficient, localized and targeted delivery to the desired tissues i.e. the skin, mucus membranes and surrounding tissues. The liposome system can be designed to provide a slow release depot at the target site within the skin or mucus membrane or localize the drug in the eye through bioadhesion and slow release or promote transdermal flux of the encapsulated drug.

Detailed Description Text (78):
In order to overcome the problems associated with the administration of PGE.sub.1 by injection, the present invention provides a new dosage form which can be applied topically. PGE.sub.1 is incorporated into liposomes which permit penetration of PGE.sub.1 through the skin of a penis to deliver a clinically useful concentration of drug into the corpus cavernosum. Liposome encapsulation enhances the penetration of the encapsulated PGE.sub.1 through the penile skin and at the same time protects the drug within the skin from premature metabolism before reaching the target site. These properties make liposomes a suitable delivery system for PGE.sub.1 in the treatment of impotence.

Detailed Description Text (79):
PGE.sub.1 is a lipid-soluble drug. Therefore, it can be encapsulated in the lipid bilayers and/or the central lipophilic core of the liposomes. The encapsulation efficiency of PGE.sub.1 into liposomes is manipulated by varying lipid composition, lipid/drug ratio, pH and the concentration of other excipients. Specific liposome compatible penetration enhancers/release agents are employed in designing an optimal liposomal PGE.sub.1 preparation for dermal or transdermal delivery.

Detailed Description Text (80):
The compositions of selected liposomal PGE.sub.1 formulations developed for transdermal delivery (Products 5, 6, 7, 8, 11 and 12--0.1%) and for dermal delivery (Products 9 and 10) are given above. The liposomal formulations for the transdermal delivery of PGE.sub.1 contain saturated and/or unsaturated phospholipids, especially phosphatidylcholine, lysophosphatidylcholine, phosphatidylserine, phosphatidylethanolamine, glycolipids. The liposomes also contain cholesterol, saturated long chain fatty acids (e.g. stearic acid) to improve physical stability and appearance of the product. The phospholipids are in combination with a penetration enhancing agent such as monolauroyllysine and/or methyl salicylate to achieve predominantly transdermal delivery potential.

Detailed Description Text (88):
For the treatment of impotence there is a requirement to deliver 5-40 .mu.g PGE.sub.1 (the equivalent amount delivered during intracavernous injection) transdermally. This amount should be delivered within short period (ideally within 1 h) to be practically useful. The data obtained shows that PGE.sub.1 can be delivered transdermally by appropriate liposomal formulas.

Detailed Description Text (89):
Table 4 shows the percutaneously delivered PGE.sub.1 in vitro through human foreskin. Products 6, 7, 8, 11 and 12--0.1% illustrate the formulation approach to

develop a transdermal product.

Detailed Description Text (90):
The initial drug concentration used in these formulas was 0.05%. Effective drug concentration in these formulas can vary between 0.01-5%. As illustrated with products 11 and 12--0.1%, increasing drug concentration to 0.1% doubled the amount of transdermally delivered PGE.sub.1.

Detailed Description Text (91):
The percutaneous absorption parameters are shown in Table 5. The flux values obtained for the products correlated well with their in vivo efficacy assessed by doppler ultrasonography. The higher flux values indicate higher potency in the patients. Products 9 and 10 show low transdermal delivery potential.

Detailed Description Text (93):
The transdermal versus dermal delivery potential of these formulations is reflected in the T/D ratio (Table 7) calculated from the mean (.mu.g) transdermally absorbed drug and the mean (.mu.g) cutaneously (whole skin count) delivered PGE.sub.1 amount.

Detailed Description Text (117):
Doppler ultrasonography was used to assess the degree of arterial dilatation and measure penile arterial blood flow following application of transdermal liposomal PGE.sub.1. Three liposomal PGE.sub.1 preparations and a placebo control were tested. Test preparations were administered at no less than 2 week intervals. After initial sonographic examination to determine blood flow in the flaccid penis, the test preparation was applied on the shaft and glans penis after which an occlusive wrapping was placed around the penis. The penile blood flow was monitored at 15 minute intervals for 1 hour.

Detailed Description Text (118):
The doppler ultrasonography study on patients with predominantly organic impotence showed increased penile blood flow after topical liposomal PGE.sub.1 application (Table 9), Liposome product 11 showed the greatest efficacy, with a peak flow of 32 cm/s in Patient #4. The control liposome 11 formulation (without PEG.sub.1) also exhibited an increase in penile blood flow. The 11 liposome preparation is equivalent to product 8 plus a penetration enhancing agent, methyl salicylate. It is likely that this penetration enhancer increases penile blood flow to a small degree by itself and is synergistic with liposomal PGE.sub.1. The in vitro percutaneous absorption data correlated very well with the doppler results. In vitro product 11 liposomal PGE.sub.1 gave the highest percutaneous flux followed by product 8 and lastly, the product 13 liposomal PGE.sub.1 formulation.

Detailed Description Text (120):
Other possible uses for topically applied liposomal PGE.sub.1 include the preparation of transdermal formulations for the treatment of impotence as well as the preparation of dermal formulations for the treatment of various skin conditions such as atopic skin, psoriasis, peripheral vascular diseases, wound healing and ischaemic lesions.

Detailed Description Text (121):
TOPICAL LIPOSOME-ENCAPSULATED INTERFERON ALPHA FOR THE TREATMENT OF GENITAL PAPILLOMAVIRUS INFECTIONS

Detailed Description Text (130):
The first patient was a 30-year old female with a three-year history of recurrent genital HPV with cervical involvement (CIN I). On examination prior to instituting topical IFN alpha (F#2) therapy, large confluent plaques and separate verrucous and filiform papules typical for condylomata acuminata were present on the labia majora, labia minora and upper thighs. Histopathology showed condyloma with mild

intraepithelial atypia. VIRA-PAP was positive for HPV 6/11. In situ hybridization showed positivity for HPV 6/11, faint reactivity for HPV 31, 33 and 35, negative for HPV 16/18. Treatment protocol was as follows 3.times.10.sup.6 IU/week liposome encapsulated Intron A for 12 weeks, then 10.times.10.sup.6 IU/week for 6 weeks; 1 g twice a day externally, and 1 g once a day intravaginally. The second patient was a 23-year old male with a two-year history of genital HPV. On examination there were multiple flat flesh-colored papules scattered over the shaft, foreskin and glans of the penis. Almost all of the lesions were acetowhite after five minutes of acetic acid soaking. Histopathology showed acanthosis, koilocytes, inflammation. VIRA-PAP was positive for HPV 6/11, negative for HPV 16/18, 31, 33 and 35. In situ hybridization was negative for 6/11; 16/18; 31, 33 and 35. Treatment protocol 3.times.10.sup.6 IU/week liposome encapsulated Intron A for 8 weeks, 1 g twice a day externally. Assessment in both cases was carried out by monitoring the size and number of lesions, histopathology and in situ hybridization.

Detailed Description Text (134):
Details of formulation of liposomal products containing interferons and intended for topical application are given in Table 10.

Detailed Description Text (150):
We conclude that liposomes are a suitable delivery system for IFN alpha and a dermatologically acceptable dosage form. Our preliminary clinical studies indicate the efficacy of topically applied liposome encapsulated IFN alpha in the treatment of genital HPV infections.

Detailed Description Paragraph Table (31):
TABLE 7 Transdermal versus dermal delivery ratios for liposomal PGE.sub.1 products Product # Transdermal/Dermal delivery ratios 6 0.561 7 0.135 8 0.335 11 0.708 12- 0.1% 0.332 9 0.035 10 0.060

Detailed Description Paragraph Table (34):
TABLE 10
Formulation of topical liposomal IFN products. PRODUCT METHOD OF ENCAPSULATION NO. Lipid phase mg/g product Aqueous phase .mu.l/g product MANUFACTURE EFFICIENCY*

1
Phospholipon 90H 70 10.48 IFN stock Fusion 55.9 .+-. 1.5% Cholesterol 18 Stearic acid (20 .times. 10.sup.6 IU) Propylene glycol 70 H.sub.2 O q.s. 2 Phospholipon 90H 10.48 IFN stock 57.8% Cholesterol evaporation Stearic acid (20 .times. 10.sup.6 IU) Propylene glycol H.sub.2 O q.s. 3 Phospholipon 90H 100 10.48 IFN stock 57.3% Cholesterol 18 Oleic acid (20 .times. 10.sup.6 IU) Stearic acid H.sub.2 O q.s. Erucic acid 6 Ascorbyl palmitate 0.5 Propylene glycol 70 4 Phospholipon 90 5.24 IFN stock Fusion Ascorbyl palmitate 1 H.sub.2 O q.s. 5 Phospholipon 90H 100 10.48 IFN stock 59.2% Cholesterol 20 Stearic acid (20 .times. 10.sup.6 IU) Bovine brain extract H.sub.2 O q.s. Type VIII 5 Propylene glycol 70 6 Phospholipon 90H 10.48 IFN stock 69.8 .+-. 2.3% 50olipon 90 (20 .times. 10.sup.6 IU) H.sub.2 O q.s.ract 10ype III 70lene glycol 7 Phospholipon 90H 10.48 IFN stock 65.9% Phospholipon 90 50 (20 .times. 10.sup.6 IU) PBS q.s. 70lene glycol 8 Phospholipon 90H 10.48 IFN stock 79.0% 50olipon 90 (20 .times. 10.sup.6 IU) PBS q.s. Propylene glycol 70 9 Phospholipon 90H 10.48 IFN stock 77.8 .+-. 1.3% 50olipon 90 (20 .times. 10.sup.6 IU) PBS q.s. Propylene glycol 70 10 Phospholipon 90H 100 10.48 IFN stock 47.0 .+-. 1.3% 20 (20 .times. 10.sup.6 IU) PBS q.s.ol 11 Phospholipon 90H 100 10.48 IFN stock 75.2% 10 COMPOUND A (20 .times. 10.sup.6 IU) PBS q.s. Cholesterol Propylene glycol 70 12 Phospholipon 90H 10.48 IFN stock 45.7% 50 Phospholipon 90 (20 .times. 10.sup.6 IU) PBS q.s. Cholesterol Propylene glycol 70 13 Phospholipon 90 10.48 IFN stock 73.1% COMPOUND A 20 (20 .times. 10.sup.6 IU) PBS q.s. Propylene glycol 14 Phospholipon 90H 100 10.48 IFN stock 54.8% Centrolex P 10 (20 .times. 10.sup.6 IU) PBS q.s. Propylene glycol

*encapsulation efficiency measurerments are the average of 2-5 separate experiments

COMPOUND A = dipalmitoyllysine COMPOUND B = monolauroyllysine

Detailed Description Paragraph Table (41):

TABLE 17

Treatment of excised condyloma tissues with low-dose topical liposomal IFN alpha (F#10-80) for 24 h. Condyloma Size .phi. Surface area IFN applied IFN in WHOLE IFN in deeper lesion # (mm) Weight (cm.sup.2) (IU) layers (IU)

DOSE

REGIMEN I: 1 5 0.0794 0.78 560,000 29,800 25,700 2 0.0509 0.50 29,200 3 0.0542 1.54 13,100 4 0.07885 0.64 57,800 5 0.0807 0.78 25,300 6 0.0621 1.54 13,900 7 0.0766 1.13 37,700 Average 5.5 0.0689 0.95 34,400 .+-. 18,100 29,000 .+-. 15,300 (5.5% of total (6.5% of total applied) applied) DOSE REGIMEN II: 8 6 0.0925 1.13 1.34 .times. 10.sup.6 65,300 56,700 9 0.1235 2.01 525,1000.sup.6 464,700 10 0.1845 4.52 380,2000.sup.6 338,200 Average 8.7 0.1335 2.55 323,500 .+-. 235,100 286,500 .+-. 208,900 (9.5% of total (14.8% of total applied) applied)

Other Reference Publication (1):

Uekama, K. et al., "Improved Transdermal Delivery of Prostaglandin E.sub.1 Through Hairless Mouse Skin: Combined Use of Carboxymethyl-ethyl-.beta.-Cyclodextrin and Penetration Enhancers," Communications. 119-121 (1991).

Other Reference Publication (2):

Watkinson, A.C. et al., "Aspects of the Transdermal Delivery of Prostaglandins," International Journal of Pharmaceutics. 74 229-236 (1991).

Other Reference Publication (3):

Adam C. Watkinson et al., "Aspect of the Transdermal Delivery of Prostaglandins": International Journal of Pharmaceutics, 74 (1991); pp. 229-236.

Other Reference Publication (4):

Kaneto Uekama et al., "Improved Transdermal Delivery of Prostaglandin E.sub.1 through Hairless Mouse Skin: Combined Use of Carboxymethyl-ethyl-.beta.-Cyclodextrin and Penetration Enhances"; Communications (1991): pp. 119-121.

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